UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JEANINE SORTISIO and STEVEN R. SORTISIO

Plaintiffs

vs.

Civil No. 09 CV 0176A

PETER ACCETTA, M.D.,
SUSAN M. PETERSON, RPA-C,
ASTELLAS PHARMA US, INC., and
NOVARTIS PHARMACEUTICALS CORPORATION

Defendants

MEMORANDUM OF LAW

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PRELIMINARY STATEMENT

This Memorandum is in further support of Plaintiffs' motion to remand this matter back to the New York State Supreme Court, Erie County for further proceedings. .

The Plaintiffs respectfully submit that under the prevailing case law, defendant's removal petition is defective due to the lack of subject matter jurisdiction of the parties and requires this case to be remanded back to New York State Supreme Court. Defendant's use of the authorities cited in its papers in support of its position are both misplaced and provide an inaccurate representation of the state of the prevailing law with respect to the issues in dispute.

ARGUMENT

POINT I: FEDERAL SUBJECT MATTER JURISDICTION DOES NOT EXIST

The case law with regard to federal subject matter jurisdiction makes clear that conferring such jurisdiction is to be done only under narrow circumstances. Furthermore, the case authority on this issue makes apparent that the application of federal jurisdiction attempted to be claimed by the defendant is not proper.

As noted by the Court in *Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804, 815, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986), "the novelty of an FDCA issue is not sufficient to give it status as a federal cause of action; nor should it be sufficient to give a state-based FDCA claim status as a jurisdiction-triggering federal question."

The Defendant's use *Grable & Sons Metal Products v. Darue Engineering & Manufacturing*, 545 U.S. 308, 125 S.Ct. 2363 (2005) in its attempt to widen the scope of federal jurisdiction to the case at bar is not an accurate depiction of the Court's findings as it relates the

circumstances of the case at bar. The Court in *Grable* cited with approval the Court's prior decision in *Merrell Dow* and noted the consideration as to the application of federal questions jurisdiction:

> The Court saw the missing cause of action not as a missing federal door key, always required, but as a missing welcome mat, required in the circumstances, when exercising federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues. For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases…One only needed to consider the treatment of federal violations generally in garden variety state tort law. "The violations of federal statutes and regulations is commonly given negligence per se effect in state tort proceedings."(citations omitted)…A general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would thus have heralded a potentially enormous shift of traditionally state cases into federal courts. Expressing concern over the "increased volume of federal litigation," and noting the importance of adhering to "legislative intent," *Merrell Dow* thought it improbable that the Congress, having made no provision for a federal cause of action, would have meant to welcome any state-law case implicating federal law "solely because the violation of the federal statute is said to [create] a rebuttable presumption of [negligence] under state law. (citations omitted). In this situation, no welcome mat meant keep out. *Merrell Dow*'s analysis thus fits within the framework of examining the importance of having a federal forum for the issue, and the consistency of such a forum with Congress's intended division of labor between state and federal courts. *Grable* at 318.

The Court's further noted later case of *Empire Healthchoice Assurance v. McVeigh*, 547 U.S. 677, 701, 126 S.Ct. 2121 (2006), "*Grable* emphasized that it takes more than a federal element to 'to open the 'arising under' door." (citations omitted) in finding the lack of federal jurisdiction under the "**slim** category that *Grable* exemplifies" (emphasis added).

The Plaintiffs' complaint pleads only causes of action and claims for damages for negligence, express and implied warranties and strict products liability pursuant to New York State law. The Defendant, in its efforts to justify its petition, relies entirely on a severely

misconstrued interpretation of just one paragraph of the Plaintiffs' complaint. The Defendant's arguments grossly stretch the plain language of paragraph 13 of the complaint in their attempt to justify the Defendant's removal petition. The Defendant first essentially attempts to claim that the paragraph states a reliance on a demonstration a violation of the drug approval process with the Food and Drug Administration as the only basis of its entire action. However, as previously noted, the Plaintiffs allege potential violations as a merely one of the circumstance underlining its state law claims. It is clear that the paragraph mentioned is only part of Plaintiffs' claim outlining its negligence cause of action and furthermore is only one of three paragraphs setting forth Plaintiffs' claims which frame the issues of their cause of action for negligence (See paragraphs 14 and 15). See *Broder v. Cablevision Systems Corporation*, 418 F3d 187 (2nd Cir. 2005) ("Where a federal issue is present as only one of multiple theories that could support a particular claim…this is insufficient to create federal jurisdiction."(citations omitted)).

Plaintiffs' complaint claims no cause of action for fraud nor a seeking of remedies under the Food Drug and Cosmetic Act (FDCA). Furthermore, as noted under *Merrell Dow*, the Plaintiffs can not seek a cause of action for their claims under the FDCA nor is proof of an improperly obtained approval of the products by the Food and Drug Administration required for Plaintiff's state law causes of action to prevail. Additionally, the defendant also claims that this paragraph somehow sets forth a separate cause of action for fraud which again is another gross interpretation and exaggeration of the language of plaintiff's complaint. A claim for fraud is separate and distinct with its own requirements for the claiming and demonstration of such a cause of action. The plaintiff sets forth no claims or claim for damages on a cause of action for

fraud. Furthermore, even under defendant's contorted interpretation of paragraph 13, this in and of itself does not demonstrate the presence of federal jurisdiction.

The similar efforts to the ones made by Defendant Astellas in its petition, have been attempted before and rejected. The defendant in *Sullivan v. Novartis Pharmaceuticals Corp.*, 575 F.Supp.2d. 640 (D.N.J.), who also is a defendant in this case, attempted to make similar arguments to the ones attempted by Defendant Astellas. In finding that federal jurisdiction should not be conveyed the Court in *Sullivan*, considered "that the federal issues potentially raised in the instant case are no more substantial than those raised in *Merrell Dow* and… the *Grable*'s Court's praise for *Merrell Dow*'s effect from protecting the federal system from a significant disturbance in the federal-state workload balance…" Id. at 650. See also *Sullivan v. Novartis Pharmaceuticals Corp.*, 602 F.Supp.2d 527 (D.N.J. 2009) ("Defendant's argument in support of federal jurisdiction is not a novel one. To the contrary, it is one that has been repeatedly and uniformly rejected.")

Buckman v. Plaintiffs' Litigation Committee, 531 U.S. 341 (2001), relied upon the defendant is distinguishable from the case at bar. As an initial matter, *Buckman* was not a pharmaceutical case but rather a medical products case which examined the issue of preemption specifically with regard to the Medical Device Amendment of the FDCA. It is important to note that complete preemption has not been found with respect to the FDCA. See *Wyeth v. Levine*, 129 S.Ct. 1187 (2009); *DeAngelo-Shuayto v. Organon USA Inc.*, 2007 WL 4365311 (D.N.J.). Furthermore, the issue in *Buckman* concerned ordinary preemption as opposed to an examination of "arising under" analysis in consideration of federal question jurisdiction which is the issue before this Court. Further stated, "*Buckman* does not make any holding with regard to the

existence of federal question jurisdiction over a case by virtue of a state law claim that incorporates federal law as setting forth the standard of the offending conduct." *DeAngelo-Shuayto v. Organon USA Inc.*, 2007 WL 4365311 (D.N.J.). The defendant's reliance on *Grange v. Mylan Laboratories, Inc.*, 2008 WL 4813311 (D.Utah), *Kobar v. Novarits Corp.*, 378 F.Supp.2d 1166 (D.Ariz. 2006) and related authorities are misplaced for similar reasons.

The remainder of the cases cited by Defendant are all distinguishable from the case at bar. The cited cases in which federal jurisdiction was conveyed do not involve an individual personal injury action by a plaintiff alleging personal injuries as a result of the ingestion of a pharmaceutical product under the circumstances they claim in their present petition. Accordingly, what is telling in the Defendant's papers is what is not cited. There are many personal injury lawsuits filed by plaintiffs each year alleging injuries caused by pharmaceutical products. The Defendant fails to cite one case in which a Court found federal question jurisdiction under the circumstances it attempts to espouse in this matter.

CONCLUSION

Based on the above, Plaintiffs respectfully request an Order of this Court remanding the action to the New York State Supreme Court, Erie County.

DATED: Lancaster, New York
May 13, 2009

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I hereby certify that on May 13, 2009, I electronically filed Plaintiff's Memorandum of Law in the above captioned matter with the Clerk of the District Court using its CM/ECF system which would electronically notify the following CM/ECF participants: Scott R. Jennette, Esq.; Sharon M. Porcellio, Esq.; Harvey L. Kaplan, Esq.; Mark C. Hagerty, Esq.; Harry F. Mooney, Esq., Peter J. Skalaban Jr., Esq., Katharine R. Latimer, Esq. and Susan A. Eberle, Esq.

DATED: May 13, 2009
Lancaster, New York

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